K000852

ANS

JAN 1 9 2001

510 (k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared:	March 10, 2000
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ANS

Peripheral Nerve Stimulation System
510(k) Summary of Safety and Effectiveness

Device Information:

Trade Names:	Renew ™ Quattrode® Percutaneous Lead Kit
Common Name:	Implanted Spinal Cord Stimulators
Classification Name:	Stimulator, Spinal Cord, Implanted (Pain Relief)
	Stimulator, Peripheral Nerve, Implanted (Pain Relief)

Predicate Devices:

Medtronic, Inc. On-Point™ lead (Model 3987/3988) and Resume II™ lead Model 3587A and Model 3080 under 510(k) K982902 and K915540. ANS Renew Quattrode leads under K960728 and K991784.

Device Description:

The ANS percutaneous lead consists of a variety of platinum iridium electrodes on the distal end connected by individually insulated wires to platinum iridium contact bands on the proximal end. The leads are made from the same biocompatible material as the ANS current device.

Intended Use:

ANS Renew leads are indicated for the treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. ANS Renew leads are also indicated to stimulate electrically peripheral nerves to relieve severe intractable pain. The leads are intended to be used with ANS, extensions, receivers, transmitters, and antennae.

Comparison to Predicate Device:

The following table illustrates the substantial equivalence between the modified device and the predicate, Medtronic's On-Point lead, Resume lead and ANS current leads.

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	Medtronic's On-Point Leads 3987/3988, Resume Lead II 3587A, Model 3080	ANS Current Lead Devices	ANS Devices Under Review: 3143, 3146, 3153, 3156
	Predicate Device		
510(k) Number:	**K982902, K915540**	**K960728, K991784**	
Intended Use:	The treatment of chronic pain of trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The leads are also indicated to stimulate electrically peripheral nerves to relieve severe intractable pain.	Stimulation of spinal cord for chronic, intractable pain of trunk and limbs.	Same as Medtronic predicate devices.
Materials • Electrode: • Insulator:	 Platinum/Iridium Polyurethane and Silicone Rubber	 Same Polyurethane	 Same Polyurethane
Design Features:	Multielectrode Multiconductor Coil, Each Conductor Individually Insulated 4 Platinum/Iridium Electrodes Flat-Shaped Electrodes	Same Braided Wire Cable Same Cylindrical-Shaped	Same Braided Wire Cable Same Cylindrical-Shaped
Dimensions • Lead Length: • Diameter: • Array Length:	 18 cm 1.4 mm Thickness 34 mm	 30 cm, 60 cm 1.37 mm Thickness 24 mm	 30 cm, 60 cm 1.37 mm Thickness 24 mm
Method of Introduction:	Surgical	Percutaneous	Percutaneous
Tissue Contact:	Yes	Same	Same
Sterilization:	Sterile (ETO)	Same Sterility Assurance Level (SAL) 1×10^{-6}	Same Same
Labeling:	Labeled as Sterile, Prescription Device	Same	Same
Package:	Blister Tray/Tyvek Lid	Same	Same

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Electrical Characteristics:

The output parameters of the ANS RF spinal cord stimulation system are all within the ANSI standards. The standard was established under ANSI/AAMI NS-1995 that outlines safe stimulation parameters for PNS.

1. Pulse Frequency—1 to 1,500 pps
2. Pulse Width—1 to 2,000 μsec
3. Amplitude Voltage (Current)—1 to 15 volts or 0 to 30 mA through a 500-ohm load.

The current output ranges of the ANS device are pulse width range 50 to 500 μsec, frequency range 10 to 1500 Hz, and amplitude range 0 to 12 V. The electrode surface area is approximately 0.13 cm^2. At maximum output, the current density is 92.3 μC/ cm^2. This current density is considered safe for platinum iridium electrodes with respect to electrode corrosion.

Nonclinical Testing:

Electrochemical evaluation was performed on ANS percutaneous lead and the results suggest that they operated within safe limits and are as safe as the predicate device.

Testing was performed for electrochemical characteristics and charge injection levels of the ANS percutaneous lead (cylindrical shape) and the predicate Medtronic Resume lead (flat). The estimated geometric surface area of the Medtronic predicate device is 0.11 cm^2, and the ANS device has an estimated surface area of 0.14 cm^2. All leads operated at or within safe limits with respect to metal dissolution during constant current pulsing at 50 Hz, 200 μs pulse width, and 58.4 mA current. The larger surface area of the percutaneous lead resulted in a smaller maximum current and consequently lower charge density giving this electrode the largest margin of electrochemical safety of the three electrodes tested. These test results suggest that the ANS percutaneous lead (cylindrical electrodes) is as safe as the Medtronic Resume lead (paddle with flat electrodes) with respect to metal dissolution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 9 2001

Mr. Rashmi Moza
Regulatory Affairs Specialist
Advanced Neuromodulation Systems, Inc.
6501 Windcrest Drive, Suite 100
Plano, Texas 75024

Re: K000852
Trade Name: ANS Renew Neurostimulation System Transmitter, Model 3508, Receiver Model 3408, Antennae Models 1220 and 1230, Lead Models 3143, 3146, 3153, 3156, 3183 and 3186, Extension Models 3382, 3383, 3341, 3342 and 3343
Regulatory Class: II
Product Code: GZF and GZB
Dated: October 20, 2000
Received: October 23, 2000

Dear Mr. Michael:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ANS

510(k) Number: K000852

Device Name: Renew Neurostimulation System

Indications for Use:

ANS Renew percutaneous leads, extensions, receivers, transmitters and antenna are indicated for spinal cord stimulation in the treatment of chronic pain of trunk and limbs, ~~either as the~~ sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. ANS Renew percutaneous leads model numbers 3143, 3146, 3153, 3156, 3183, 3186, extensions model numbers 3382, 3383, 3341, 3342, 3343, receivers model number 3408, transmitter model number 3508 and antenna model numbers 1220, 1230 are also indicated to stimulate electrically peripheral nerves to relieve severe intractable pain.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000852

Prescription Use __ Or Over-The-Counter Use __
(Per 21 CFR 801.109)

ADVANCED NEUROMODULATION SYSTEMS, INC.
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